U.S.S.N. 09/661,773
Filed: September 14, 2000
RESPONSE TO RESTRICTION REQUIREMENT

Remarks

The claims were divided into three groups, Group I, claims 1-17 and 29-32, drawn to a composition for the repair or augmentation of tissue, and for the treatment of osteoarthritic knees, comprising a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, Group II, claims 18-24, drawn to methods for repairing, contouring, or augmenting tissue, using the composition, and Group III, claims 25-28, drawn to methods for treating osteoarthritic knees, using the composition.

In response, applicants provisionally elect Group I, claims 1-17 and 29-32, with traverse. The claimed methods of group II and group III are related

The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process. MPEP § 806.04

In the present application, the claimed methods of the two groups are connected in design, operation, because both claims 18 and 25 requires selecting the object for treatment, and introducing into the object a biocompatible, bioabsorbable fluid which comprises polyhydroxyalkanoate. The claimed methods are also connected in effect: treatment of soft tissue related diseases or disorders.

Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects, are independent. An article of apparel such as a shoe, and a locomotive bearing would be an example. A process of painting a

house and a process of boring a well would be a second example. MPEP § 806.04 As discussed above, the relationship between the claimed methods of groups II and III is clearly different from that of the second example. Nevertheless, the Examiner alleged that the methods claimed in groups II and III cannot be used together and they have different modes of operation and different functions, without any explanation for the allegation. Based on the allegation, the Examiner concluded that the processes are unrelated.

Applicants respectfully disagree with the Examiner. Contrary to the assertion of the Examiner, the claimed methods of the groups II and III can be used together. For instance, if a patient has both facial defects and osteoarthritic knees in need of treatment, the claimed methods can be used together to treat both the diseases/defects of the patient.

The subject matter of group I is not distinct from either that of group II or that of group III

A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product, or (B) the product as claimed can be used in a materially different process. MPEP § 806.05(h). In the present application, the Examiner stated that the restriction is proper, because the product of group I can be used in several allegedly different process such as in group II and group III.

As discussed above, the claimed methods of the two groups are connected in design, operation, and effect. From the above discussion, it is also obvious that there is no material difference between the two claimed methods.

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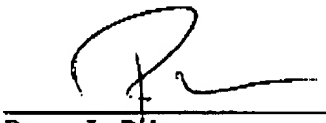
To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. (See MPEP § 803). In the present application, the Examiner failed to show that examination of groups I, II, and III together would constitute a burden to the Examiner.

Favorable consideration of all claims 1-32 is earnestly solicited.

Respectfully submitted,



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ATL1 #501554 v1

Appendix I. Claims as pending upon entry of the amendments

1. A composition for the repair or augmentation of tissue in an animal or human, comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate.

2. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid or wax at a temperature between about 20 and 25 °C.

3. The composition of claim 1 wherein the polyhydroxyalkanoate is liquid at the body temperature of the animal.

4. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid at about 37 °C.

5. The composition of claim 1 wherein the biocompatible fluid is a microdispersion of particles of the polyhydroxyalkanoate dispersed in a physiologically compatible liquid carrier.

6. The composition of claim 5 wherein the carrier is a second polyhydroxyalkanoate or an aqueous solution.

7. The composition of claim 1 wherein the particles have a diameter of less than about 500 μm.

8. The composition of claim 7 wherein the diameter is less than about 50 μm.

9. The composition of claim 8 wherein the diameter is less than about 5 μm.

10. The composition of claim 1 wherein the polymer is derived from one or more monomers selected from the group consisting of 2-hydroxybutanoate, 3-hydroxyalkanoates, 3-hydroxyalkenoates, 4-hydroxyalkanoates, 4-hydroxyalkenoates, 5-hydroxyalkanoates, 5-hydroxyalkenoates, 6-hydroxyalkanoates, and 6-hydroxyalkenoates.

11. The composition of claim 1 wherein the polyhydroxyalkanoate has a molecular weight of less than 100,000.

12. The composition of claim 11 wherein the molecular weight is less than 50,000.

13. The composition of claim 1 having a viscosity between about 1 and 100,000 cP.

14. The composition of claim 13 having a viscosity between about 1 and 10,000 cP.

15. The composition of claim 1 further comprising an agent selected from the group consisting of dyes, compounds with anti-microbial activity, anesthetics, adjuvants, anti-inflammatory compounds, surfactants, steroids, lipids, enzymes, antibodies, and hormones.

16. The composition of claim 1 further comprising a peptide or protein.

17. The composition of claim 1 wherein the polyhydroxyalkanoate is amorphous.

18. A method for repairing, contouring, or augmenting tissue in an animal comprising the steps of:

(a) selecting tissue in need of repair, contouring, or augmentation, and

(b) introducing into the tissue the composition of claim 1.

19. The method of claim 18 wherein the tissue is soft tissue.

20. The method of claim 19 for use in the treatment of urinary incontinence or vesicoureteral reflux.

21. The method of claim 19 wherein the soft tissue is facial tissue.

22. The method of claim 19 wherein the soft tissue is skin, sphincter muscle, or urinary bladder.

23. The method of claim 18 wherein the tissue is selected from the group consisting of bone, cartilage, tendon, and muscle.

24. The method of claim 18 wherein the introduction is by injection.

25. A method for treating osteoarthritic knees in an animal comprising:

(a) selecting the osteoarthritic knee in need of treatment, and

(b) introducing into the knee a composition comprising a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement.

26. The method of claim 25 wherein the polyhydroxyalkanoate is a liquid.

27. The method of claim 25 wherein the composition is introduced into the knee by injection into the knee joint.

28. The method of claim 25 wherein the composition replaces or supplements synovial fluid.

29. A composition for use in the treatment of osteoarthritic knees comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement

30. The composition of claim 28 wherein the polyhydroxyalkanoate is amorphous.

31. A kit of parts comprising

(a) the composition of claim 1; and

(b) a means for delivering the composition to a patient.

32. The kit of claim 31 wherein the means for delivering comprises a needle and a syringe.

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RESPONSE TO RESTRICTION REQUIREMENT
AND PETITION FOR EXTENSION OF TIME

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the enclosed Response to Restriction Requirement and Petition for two months Extension of Time and all documents shown as being attached is being facsimile transmitted to the U. S. Patent and Trademark Office on the date shown below.

Date: February 15, 2001

Jean Hicks

Jean Hicks

ATL1 #509068 v1